

# Device Safety

## Sending the wrong signals

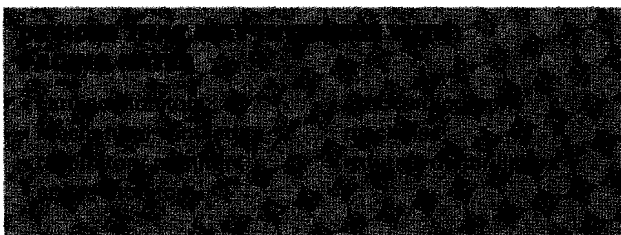
BY DIANE DWYER, RN, BSN

Nurse-Consultant • Center for Devices and Radiological Health  
Food and Drug Administration • Rockville, Md.

A PATIENT IN THE O.R. who was receiving mechanical ventilation had something in common with a patient connected to a cardiac monitoring system in the CCU. Both had implanted pacemakers and both experienced unintended maximum pacing rates up to 120 beats/minute. Medical intervention was needed to turn off the minute ventilation sensor in each pacemaker. When the sensors were turned off, the patients' heart rates returned to normal.

### What went wrong?

Minute ventilation sensor-driven pacemakers set their pacing rate by measuring thoracic impedance and adjusting pacing output accordingly. Some medical devices, including cardiac monitors and mechanical ventilators, emit a weak electrical current that may interfere with the minute ventilation sensor. In both cases, such interference appears to have led to incorrect measurement of thoracic impedance and pacemaker rate increases.



### What precautions can you take?

- If your patient has an implanted pacemaker, document the type when he's admitted to the facility. Indicate the manufacturer, model, and sensor type.
- Make sure the minute ventilation rate-adaptive sensor mode is turned off while he's connected to equipment that could interfere with the pacemaker. Carefully monitor his heart and respiratory rate.
- Share with the patient and your colleagues the Food and Drug Administrative Public Health Advisory "Interaction between Minute Ventilation Rate-Adaptive Pacemakers and Cardiac Monitoring and Diagnostic Equipment." You can get a copy at <http://www.fda.gov/cdrh/safety.html> by scrolling down to and clicking on 10-14-98. ①

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Although you need to support the adverse event-reporting policy of your health care facility, you may voluntarily report a medical device that doesn't perform as intended by calling MedWatch at 1-800-FDA-1088 (fax: 1-800-FDA-0178). The opinions and statements contained in this report are those of the author and may not reflect the views of the Department of Health and Human Services. Device Safety is coordinated by Chris Parmentier, RN.